K113758

JAN 10 2012

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	December 21, 2011
Submitter:	GE Healthcare [GE Healthcare Austria GmbH & Co OG] Tiefenbach 15 Zipf, Austria 4871
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare T:(414)721-4214 F:(414)918-8275
Secondary Contact Person:	Roland Kuntscher Regulatory Affairs Specialist GE Healthcare Austria GmbH & Co OG T:(++43)7682-3800-660 F:(++43)7682 3800-47
Device: Trade Name:	Voluson E6/E8/E8Expert/E10 Diagnostic Ultrasound System
Common/Usual Name:	Voluson E6/E8/E8Expert/E10
Classification Names:	Class II
Product Code:	Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Predicate Device(s):	K112213 Voluson E6/E8/E8Expert/E10 Diagnostic Ultrasound System
Device Description:	The Voluson E6/E8/E8Expert/E10 system is a full-featured Track 3 ultrasound system, primarily for general radiology use and specialized for OB/GYN with particular features for realtime 3D/4D acquisition. It consists of a mobile console with keyboard control panel; color LCD/TFT touch panel, color video display and optional image storage and printing devices. It provides high performance ultrasound imaging and analysis and has comprehensive networking and DICOM capability. It utilizes a variety of linear, curved linear, matrix phased array transducers including mechanical and electronic scanning transducers, which provide highly accurate realtime three dimensional imaging supporting all standard acquisition modes.
Intended Use:	The device is a general purpose ultrasound system. Specific clinical applications remain the same as previously cleared:

Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid etc.); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Peripheral Vascular; Transvaginal; Transrectal; and Intraoperative (abdominal, PV and neurological).

Technology: The Voluson E6/E8/E8Expert/E10 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform with applicable medical device safety standards. The Voluson E6/E8/E8Expert/E10 and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Voluson E6/E8/E8/ Expert/E10, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Voluson E6/E8/E8 Expert/E10 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JAN 10 2012

Mr. Bryan Behn
GE Healthcare
Regulatory Affairs Manager
9900 W Innovation Drive
WAUWATOSA WI 53226

Re: K113758
Trade/Device Name: Voluson E6/E8/E8Expert/E10 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: December 21, 2011
Received: December 21, 2011

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DUS 6000 Digital Ultrasonic Imaging System, as described in your premarket notification:

Transducer Model Number

C4-8-D
RAB6-D

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA

may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Michael O'Hara at (301) 796-0294.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known):

Device Name: Voluson E6/E8/E8Expert/E10 Diagnostic Ultrasound System

Indications for Use:

The device is a general purpose ultrasound system. Specific clinical applications remain the same as previously cleared: Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid etc.); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Peripheral Vascular; Transvaginal; Transrectal; and Intraoperative (abdominal, PV and neurological).

Prescription Use_X___ AND/OR Over-The-Counter Use_NA_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K113758

Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Voluson E6/E8/E8Expert/E10 system and for all of its probe/mode combinations. There have been no changes to the system level indications for use or modes and no new transducers have been added to the unmodified device. The only change is CW mode has been added to C4-8-D and RAB6-D via Appendix E of the Ultrasound Guidance. This was mistakenly missed in the transducer tables in K112213 and is now being corrected.

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113758

Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert/E10 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
Anatomy/Region of Interest	B	M	PW Doppler	CW Doppler	Color# Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ[2]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5]
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	[5]
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5,6,9]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	P	P	P		P	P	P	P	P	P	[5,6,9]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6,9]
Transuretheral											
Intraoperative	P	P	P		P	P	P	P	P	P	
Intraoperative Neurological	P	P	P		P	P	P	P	P	P	
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
[#] 4D color Doppler

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113758

Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert/E10 with C4-8-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	E	P	P	P	P	P	P	[6]
Abdominal[1]	P	P	P	E	P	P	P	P	P	P	[6]
Pediatric	P	P	P	E	P	P	P	P	P	P	[6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	P	P	E	P	P	P	P	P	P	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[6] Includes imaging of guidance of biopsy (2D)
[7] Includes infertility monitoring of follicle development
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)

Mary S Pastel
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Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113758

Diagnostic Ultrasound Indications for Use Form

GE Voluson E6/E8/E8Expert/E10 with RAB6-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	E	P	P	P	P	P	P	[5,6]
Abdominal[1]	P	P	P	E	P	P	P	P	P	P	[5,6]
Pediatric	P	P	P	E	P	P	P	P	P	P	[5,6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P	E	P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (3D/4D)
[7] Includes infertility monitoring of follicle development
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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